



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-2462]

The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft guidance for industry (GIF) #210 entitled “The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.” This draft guidance describes the process for adding a new animal drug to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). The Index consists of a list of legally marketed unapproved new animal drugs for minor species that meet the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-2462 for "The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species."

Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dorothy Bailey, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0565, dorothy.bailey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) (Pub. L. No. 108-282) amended the FD&C Act to provide animal drug companies with incentives to develop new animal drugs for minor species and minor uses in major species, while still ensuring appropriate safeguards for animal and human health.

One of the incentives established by the MUMS Act is the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, also referred to as “the Index.” The Index is available for new animal drugs intended for use in minor species; the Index is not available for drugs intended for minor use in major species (horses, cattle, pigs, turkeys, chickens, dogs, and cats).

The Index consists of a list of legally marketed unapproved new animal drugs for minor species that meet the requirements of section 572 of the FD&C Act (21 U.S.C. 360ccc-1). We refer to the process of adding a new animal drug to the Index as “indexing.” Indexing represents a pathway for legally marketing unapproved new animal drugs for minor species.

In the *Federal Register* of December 6, 2007, FDA published final regulations establishing administrative procedures and criteria for listing a new animal drug for use in a minor species in the Index (72 FR 69108). These regulations, which are codified at 21 CFR part 516, subpart C, are administered by the Office of Minor Use and Minor Species Animal Drug Development (OMUMS) within FDA’s Center for Veterinary Medicine (CVM). That office also maintains the Index, which is available to the public through FDA’s website at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm125452.htm>.

FDA is announcing the availability of a draft GIF #210 entitled “The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.” This draft guidance describes the process for adding a new animal drug to the Index.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 516.119 through 516.165 have been approved under OMB control number 0910-0620.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: September 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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